

Act No. 218
Public Acts of 2001
Approved by the Governor
December 27, 2001
Filed with the Secretary of State
December 28, 2001
EFFECTIVE DATE: December 28, 2001

**STATE OF MICHIGAN
91ST LEGISLATURE
REGULAR SESSION OF 2001**

Introduced by Reps. Voorhees, Vander Veen, Birkholz, Kuipers, Caul, Cassis and Shulman

ENROLLED HOUSE BILL No. 5146

AN ACT to amend 1978 PA 368, entitled "An act to protect and promote the public health; to codify, revise, consolidate, classify, and add to the laws relating to public health; to provide for the prevention and control of diseases and disabilities; to provide for the classification, administration, regulation, financing, and maintenance of personal, environmental, and other health services and activities; to create or continue, and prescribe the powers and duties of, departments, boards, commissions, councils, committees, task forces, and other agencies; to prescribe the powers and duties of governmental entities and officials; to regulate occupations, facilities, and agencies affecting the public health; to regulate health maintenance organizations and certain third party administrators and insurers; to provide for the imposition of a regulatory fee; to promote the efficient and economical delivery of health care services, to provide for the appropriate utilization of health care facilities and services, and to provide for the closure of hospitals or consolidation of hospitals or services; to provide for the collection and use of data and information; to provide for the transfer of property; to provide certain immunity from liability; to regulate and prohibit the sale and offering for sale of drug paraphernalia under certain circumstances; to provide for the implementation of federal law; to provide for penalties and remedies; to provide for sanctions for violations of this act and local ordinances; to repeal certain acts and parts of acts; to repeal certain parts of this act; and to repeal certain parts of this act on specific dates," by amending section 20155 (MCL 333.20155), as amended by 2000 PA 171.

The People of the State of Michigan enact:

Sec. 20155. (1) Except as otherwise provided in this section, the department of consumer and industry services shall make annual and other visits to each health facility or agency licensed under this article for the purposes of survey, evaluation, and consultation. A visit made pursuant to a complaint shall be unannounced. Except for a county medical care facility, a home for the aged, a nursing home, or a hospice residence, the department shall determine whether the visits that are not made pursuant to a complaint are announced or unannounced. Beginning June 20, 2001, the department shall assure that each newly hired nursing home surveyor, as part of his or her basic training, is assigned full-time to a licensed nursing home for at least 10 days within a 14-day period to observe actual operations outside of the survey process before the trainee begins oversight responsibilities. A member of a survey team shall not be employed by a licensed nursing home or a nursing home management company doing business in this state at the time of conducting a survey under this section. The department shall not assign an individual to be a member of a survey team for purposes of a survey, evaluation, or consultation visit at a nursing home in which he or she was an employee within the preceding 5 years.

(2) The department of consumer and industry services shall make at least a biennial visit to each licensed clinical laboratory, each nursing home, and each hospice residence for the purposes of survey, evaluation, and consultation. The department of consumer and industry services shall semiannually provide for joint training with nursing home surveyors and providers on at least 1 of the 10 most frequently issued federal citations in this state during the past calendar year. The department of consumer and industry services shall develop a protocol for the review of citation patterns compared to regional outcomes and standards and complaints regarding the nursing home survey process. The

review will result in a report provided to the legislature. Except as otherwise provided in this subsection, beginning with his or her first full relicensure period after June 20, 2000, each member of a department of consumer and industry services nursing home survey team who is a health professional licensee under article 15 shall earn not less than 50% of his or her required continuing education credits, if any, in geriatric care. If a member of a nursing home survey team is a pharmacist licensed under article 15, he or she shall earn not less than 30% of his or her required continuing education credits in geriatric care.

(3) The department of consumer and industry services shall make a biennial visit to each hospital for survey and evaluation for the purpose of licensure. Subject to subsection (6), the department may waive the biennial visit required by this subsection if a hospital, as part of a timely application for license renewal, requests a waiver and submits both of the following and if all of the requirements of subsection (5) are met:

(a) Evidence that it is currently fully accredited by a body with expertise in hospital accreditation whose hospital accreditations are accepted by the United States department of health and human services for purposes of section 1865 of part C of title XVIII of the social security act, 42 U.S.C. 1395bb.

(b) A copy of the most recent accreditation report for the hospital issued by a body described in subdivision (a), and the hospital's responses to the accreditation report.

(4) Except as provided in subsection (8), accreditation information provided to the department of consumer and industry services under subsection (3) is confidential, is not a public record, and is not subject to court subpoena. The department shall use the accreditation information only as provided in this section and shall return the accreditation information to the hospital within a reasonable time after a decision on the waiver request is made.

(5) The department of consumer and industry services shall grant a waiver under subsection (3) if the accreditation report submitted under subsection (3)(b) is less than 2 years old and there is no indication of substantial noncompliance with licensure standards or of deficiencies that represent a threat to public safety or patient care in the report, in complaints involving the hospital, or in any other information available to the department. If the accreditation report is 2 or more years old, the department may do 1 of the following:

(a) Grant an extension of the hospital's current license until the next accreditation survey is completed by the body described in subsection (3)(a).

(b) Grant a waiver under subsection (3) based on the accreditation report that is 2 or more years old, on condition that the hospital promptly submit the next accreditation report to the department.

(c) Deny the waiver request and conduct the visits required under subsection (3).

(6) This section does not prohibit the department from citing a violation of this part during a survey, conducting investigations or inspections pursuant to section 20156, or conducting surveys of health facilities or agencies for the purpose of complaint investigations or federal certification. This section does not prohibit the state fire marshal from conducting annual surveys of hospitals, nursing homes, and county medical care facilities.

(7) At the request of a health facility or agency, the department of consumer and industry services may conduct a consultation engineering survey of a health facility and provide professional advice and consultation regarding health facility construction and design. A health facility or agency may request a voluntary consultation survey under this subsection at any time between licensure surveys. The fees for a consultation engineering survey are the same as the fees established for waivers under section 20161(10).

(8) If the department of consumer and industry services determines that substantial noncompliance with licensure standards exists or that deficiencies that represent a threat to public safety or patient care exist based on a review of an accreditation report submitted pursuant to subsection (3)(b), the department shall prepare a written summary of the substantial noncompliance or deficiencies and the hospital's response to the department's determination. The department's written summary and the hospital's response are public documents.

(9) The department of consumer and industry services or a local health department shall conduct investigations or inspections, other than inspections of financial records, of a county medical care facility, home for the aged, nursing home, or hospice residence without prior notice to the health facility or agency. An employee of a state agency charged with investigating or inspecting the health facility or agency or an employee of a local health department who directly or indirectly gives prior notice regarding an investigation or an inspection, other than an inspection of the financial records, to the health facility or agency or to an employee of the health facility or agency, is guilty of a misdemeanor. Consultation visits that are not for the purpose of annual or follow-up inspection or survey may be announced.

(10) The department of consumer and industry services shall maintain a record indicating whether a visit and inspection is announced or unannounced. Information gathered at each visit and inspection, whether announced or unannounced, shall be taken into account in licensure decisions.

(11) The department of consumer and industry services shall require periodic reports and a health facility or agency shall give the department access to books, records, and other documents maintained by a health facility or agency to the extent necessary to carry out the purpose of this article and the rules promulgated under this article. The department shall respect the confidentiality of a patient's clinical record and shall not divulge or disclose the contents of the records in a manner that identifies an individual except under court order. The department may copy health facility or agency records as required to document findings.

(12) The department of consumer and industry services may delegate survey, evaluation, or consultation functions to another state agency or to a local health department qualified to perform those functions. However, the department shall not delegate survey, evaluation, or consultation functions to a local health department that owns or operates a hospice or hospice residence licensed under this article. The delegation shall be by cost reimbursement contract between the department and the state agency or local health department. Survey, evaluation, or consultation functions shall not be delegated to nongovernmental agencies, except as provided in this section. The department may accept voluntary inspections performed by an accrediting body with expertise in clinical laboratory accreditation under part 205 if the accrediting body utilizes forms acceptable to the department, applies the same licensing standards as applied to other clinical laboratories and provides the same information and data usually filed by the department's own employees when engaged in similar inspections or surveys. The voluntary inspection described in this subsection shall be agreed upon by both the licensee and the department.

(13) If, upon investigation, the department of consumer and industry services or a state agency determines that an individual licensed to practice a profession in this state has violated the applicable licensure statute or the rules promulgated under that statute, the department, state agency, or local health department shall forward the evidence it has to the appropriate licensing agency.

(14) The department of consumer and industry services shall report to the appropriations subcommittees, the senate and house of representatives standing committees having jurisdiction over issues involving senior citizens, and the fiscal agencies on March 1 of each year on the initial and follow-up surveys conducted on all nursing homes in this state. The report shall include all of the following information:

- (a) The number of surveys conducted.
- (b) The number requiring follow-up surveys.
- (c) The number referred to the Michigan public health institute for remediation.
- (d) The number of citations per nursing home.
- (e) The number of night and weekend complaints filed.
- (f) The number of night and weekend responses to complaints conducted by the department.
- (g) The average length of time for the department to respond to a complaint filed against a nursing home.
- (h) The number and percentage of citations appealed.
- (i) The number and percentage of citations overturned or modified, or both.

(15) The department of consumer and industry services shall report annually to the standing committees on appropriations and the standing committees having jurisdiction over issues involving senior citizens in the senate and the house of representatives on the percentage of nursing home citations that are appealed and the percentage of nursing home citations that are appealed and amended through the informal deficiency dispute resolution process.

(16) Subject to subsection (17), a clarification work group comprised of the department of consumer and industry services in consultation with a nursing home resident or a member of a nursing home resident's family, nursing home provider groups, the American medical directors association, the department of community health, the state long-term care ombudsman, and the federal centers for medicare and medicaid services shall clarify the following terms as those terms are used in title XVIII and title XIX and applied by the department to provide more consistent regulation of nursing homes in Michigan:

- (a) Immediate jeopardy.
- (b) Harm.
- (c) Potential harm.
- (d) Avoidable.
- (e) Unavoidable.

(17) All of the following clarifications developed under subsection (16) apply for purposes of subsection (16):

(a) Specifically, the term "immediate jeopardy" means "a situation in which immediate corrective action is necessary because the nursing home's noncompliance with 1 or more requirements of participation has caused or is likely to cause serious injury, harm, impairment, or death to a resident receiving care in a nursing home".

(b) The likelihood of immediate jeopardy is reasonably higher if there is evidence of a flagrant failure by the nursing home to comply with a clinical process guideline adopted under subsection (18) than if the nursing home has substantially and continuously complied with those guidelines. If federal regulations and guidelines are not clear, and if the clinical process guidelines have been recognized, a process failure giving rise to an immediate jeopardy may involve an egregious widespread or repeated process failure and the absence of reasonable efforts to detect and prevent the process failure.

(c) In determining whether or not there is immediate jeopardy, the survey agency should consider at least all of the following:

(i) Whether the nursing home could reasonably have been expected to know about the deficient practice and to stop it, but did not stop the deficient practice.

(ii) Whether the nursing home could reasonably have been expected to identify the deficient practice and to correct it, but did not correct the deficient practice.

(iii) Whether the nursing home could reasonably have been expected to anticipate that serious injury, serious harm, impairment, or death might result from continuing the deficient practice, but did not so anticipate.

(iv) Whether the nursing home could reasonably have been expected to know that a widely accepted high-risk practice is or could be problematic, but did not know.

(v) Whether the nursing home could reasonably have been expected to detect the process problem in a more timely fashion, but did not so detect.

(d) The existence of 1 or more of the factors described in subdivision (c), and especially the existence of 3 or more of those factors simultaneously, may lead to a conclusion that the situation is one in which the nursing home's practice makes adverse events likely to occur if immediate intervention is not undertaken, and therefore constitutes immediate jeopardy. If none of the factors described in subdivision (c) is present, the situation may involve harm or potential harm that is not immediate jeopardy.

(e) Specifically, "actual harm" means "a negative outcome to a resident that has compromised the resident's ability to maintain or reach, or both, his or her highest practicable physical, mental, and psychosocial well-being as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services". Harm does not include a deficient practice that only may cause or has caused limited consequences to the resident.

(f) For purposes of subdivision (e), in determining whether a negative outcome is of limited consequence, if the "state operations manual" or "the guidance to surveyors" published by the federal centers for medicare and medicaid services does not provide specific guidance, the department may consider whether most people in similar circumstances would feel that the damage was of such short duration or impact as to be inconsequential or trivial. In such a case, the consequence of a negative outcome may be considered more limited if it occurs in the context of overall procedural consistency with an accepted clinical process guideline adopted pursuant to subsection (18), as compared to a substantial inconsistency with or variance from the guideline.

(g) For purposes of subdivision (e), if the publications described in subdivision (f) do not provide specific guidance, the department may consider the degree of a nursing home's adherence to a clinical process guideline adopted pursuant to subsection (18) in considering whether the degree of compromise and future risk to the resident constitutes actual harm. The risk of significant compromise to the resident may be considered greater in the context of substantial deviation from the guidelines than in the case of overall adherence.

(h) To improve consistency and to avoid disputes over "avoidable" and "unavoidable" negative outcomes, nursing homes and survey agencies must have a common understanding of accepted process guidelines and of the circumstances under which it can reasonably be said that certain actions or inactions will lead to avoidable negative outcomes. If the "state operations manual" or "the guidance to surveyors" published by the federal centers for medicare and medicaid services is not specific, a nursing home's overall documentation of adherence to a clinical process guideline with a process indicator adopted pursuant to subsection (18) is relevant information in considering whether a negative outcome was "avoidable" or "unavoidable" and may be considered in the application of that term.

(18) Subject to subsection (19), the department, in consultation with the clarification work group appointed under subsection (16), shall develop and adopt clinical process guidelines that shall be used in applying the terms set forth in subsection (16). The department shall establish and adopt clinical process guidelines and compliance protocols with outcome measures for all of the following areas and for other topics where the department determines that clarification will benefit providers and consumers of long-term care:

- (a) Bed rails.
- (b) Adverse drug effects.
- (c) Falls.
- (d) Pressure sores.
- (e) Nutrition and hydration including, but not limited to, heat-related stress.
- (f) Pain management.
- (g) Depression and depression pharmacotherapy.
- (h) Heart failure.
- (i) Urinary incontinence.
- (j) Dementia.
- (k) Osteoporosis.
- (l) Altered mental states.
- (m) Physical and chemical restraints.

(19) The department shall create a clinical advisory committee to review and make recommendations regarding the clinical process guidelines with outcome measures adopted under subsection (18). The department shall appoint physicians, registered professional nurses, and licensed practical nurses to the clinical advisory committee, along with

professionals who have expertise in long-term care services, some of whom may be employed by long-term care facilities. The clarification work group created under subsection (16) shall review the clinical process guidelines and outcome measures after the clinical advisory committee and shall make the final recommendations to the department before the clinical process guidelines are adopted.

(20) The department shall create a process by which the director of the division of nursing home monitoring or his or her designee or the director of the division of operations or his or her designee reviews and authorizes the issuance of a citation for immediate jeopardy or substandard quality of care before the statement of deficiencies is made final. The review shall be to assure that the applicable concepts, clinical process guidelines, and other tools contained in subsections (17) to (19) are being used consistently, accurately, and effectively. As used in this subsection, "immediate jeopardy" and "substandard quality of care" mean those terms as defined by the federal centers for medicare and medicaid services.

(21) The department may give grants, awards, or other recognition to nursing homes to encourage the rapid implementation of the clinical process guidelines adopted under subsection (18).

(22) The department shall assess the effectiveness of the amendatory act that added this subsection. The department shall file an annual report on the implementation of the clinical process guidelines and the impact of the guidelines on resident care with the standing committee in the legislature with jurisdiction over matters pertaining to nursing homes. The first report shall be filed on July 1 of the year following the year in which the amendatory act that added this subsection takes effect.

(23) The department of consumer and industry services shall instruct and train the surveyors in the use of the clarifications described in subsection (17) and the clinical process guidelines adopted under subsection (18) in citing deficiencies.

(24) A nursing home shall post the nursing home's survey report in a conspicuous place within the nursing home for public review.

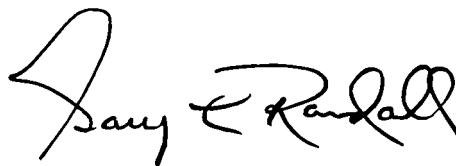
(25) Nothing in this amendatory act shall be construed to limit the requirements of related state and federal law.

(26) As used in this section:

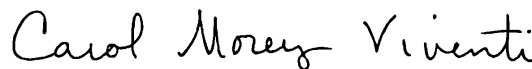
(a) "Title XVIII" means title XVIII of the social security act, chapter 531, 49 Stat. 620, 42 U.S.C. 1395 to 1395b, 1395b-2, 1395b-6 to 1395b-7, 1395c to 1395i, 1395i-2 to 1395i-5, 1395j to 1395t, 1395u to 1395w, 1395w-2 to 1395w-4, 1395w-21 to 1395w-28, 1395x to 1395yy, and 1395bbb to 1395ggg.

(b) "Title XIX" means title XIX of the social security act, chapter 531, 49 Stat. 620, 42 U.S.C. 1396 to 1396f, 1396g-1 to 1396r-6, and 1396r-8 to 1396v.

This act is ordered to take immediate effect.



Clerk of the House of Representatives.



Secretary of the Senate.

Approved

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Governor.